

**#7**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE LITIGATION

MDL NO. 1456

C.A. NO. 01-CV-12257-PBS  
Judge Patti B. Saris

THIS DOCUMENT RELATES TO:

*County of Suffolk v. Abbot Laboratories, Inc.,  
et al.*, E.D. NY No. 03-229

**MEMORANDUM IN SUPPORT OF  
MOTION TO DISMISS OF DEFENDANT BIOGEN, INC.**

Defendant Biogen, Inc. ("Biogen") respectfully submits this Memorandum of Law in Support of the Motion to Dismiss the above action brought by the County of Suffolk ("Suffolk County Action"). Biogen, which has never been named as a defendant in any other action in this MDL, including the Amended Master Consolidated Complaint ("AMCC"), has been caught up as a defendant in the Suffolk County Action based on no particularized factual allegations but simply on a theory of "guilt by association."

Thus, in addition to the reasons set forth in the consolidated memorandum filed on behalf of all defendants in support of the Motion to Dismiss, and the individual memoranda submitted by the other defendants in the Suffolk County Action, each of which Biogen joins in and incorporates by reference, the fraud-based claims against Biogen must be dismissed pursuant to Fed. R. Civ. P. 9(b). Plaintiff simply has failed to allege with sufficient particularity that Biogen fraudulently reported a false Average Wholesale Price ("AWP") for its drug Avonex® (Interferon beta-1a) or fraudulently reported a false best price or average

manufacturer price for Avonex®.<sup>1</sup> Absent any factual allegations particular to Biogen or Avonex®, Suffolk County simply may not proceed against Biogen with its fraud-based claims.

## ARGUMENT

### I. Background of Medicaid Claims.

Suffolk County brings this action to recover alleged pharmaceutical overpayments it made under the federal Medicaid program. Despite the confusing conflation of Suffolk County's factual allegations with the allegations made by the private class action plaintiffs in the AMCC, this case is *not* a Medicare case but is solely a Medicaid case. Suffolk County claims that it has overpaid its "share" of Medicaid costs for Avonex® because Biogen allegedly (1) fraudulently inflated its AWP for Avonex®, thus raising the reimbursement amount of which Suffolk County pays a percentage; and (2) fraudulently reported a false best price (BP) and average manufacturer price (AMP) for Avonex®, thus lowering Suffolk County's share of any rebate under the Medicaid rebate statute.

Three key allegations underlie Suffolk County's claims. First, that the defendants published AWP's for their products that "did not reflect the actual prices for the drugs" in order to "create an illegal kickback to the providers" and thus "market" the spread between the AWP and the real cost of the product. (Suff. Cty. Compl. ¶ 82.) Second, that the defendants "routinely do not report the actual 'best price' but, instead, exclude[] from best price discounts, free samples and other inducements . . . ." (*Id.* ¶ 84). Finally, that defendants engage in other conduct designed to "stimulate sales of their drug" including "education grants, volume discounts, . . . rebates or free goods," and "free samples." (*Id.* ¶¶ 82-87.) However, Suffolk County fails to make *any particularized factual allegation* that

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<sup>1</sup> Avonex® is the only drug manufactured and sold by Biogen at issue, or indeed even referenced, in the Suffolk County Action.

*Biogen* engaged in any of the above conduct. That failure requires the dismissal of each of the fraud-based claims against *Biogen*.

## **II. The Fraud-Based Claims Against Biogen Must Be Dismissed.**

Pursuant to Fed. R. Civ. P. 9(b), to properly allege claims of fraud, a plaintiff must plead the “who, what, where, and how” of the alleged fraud. See United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 46 (D. Mass. 2001); see also Powers v. Boston Cooper Corp., 926 F.2d 109, 111 (1st Cir. 1991) (plaintiff must specify the “time, place and content of the alleged false or fraudulent representations.”) It is not sufficient to “salt the complaint with the words ‘falsely’ and ‘fraudulently’.” Curtis v. Duffy, 742 F. Supp. 34, 38 (D. Mass. 1990).<sup>2</sup> The fraud-based claims against *Biogen* fail to satisfy these stringent standards of Rule 9(b).

### **A. Plaintiff Fails to Allege with Particularity that Biogen Improperly Inflated the AWP for Avonex®.**

The only basis for Plaintiff’s claim that *Biogen* reported a false AWP for *Avonex*® is an unspecified “investigation.” (See Suff. Cty Compl. ¶¶ 7, 189 and Ex. A.) As a result of that “investigation,” which is not described at all in the Complaint, Suffolk County has come up with an “estimated true AWP” for *Avonex*. (See Id. ¶ 189 and Ex. A.) Thus, Suffolk County alleges that for 2001, *Biogen* reported an AWP for *Avonex* of \$1,076.25 and that the true AWP was \$752.69. (Id.) Suffolk County *never* describes how it determined the “estimated true AWP,” or, more importantly, identifies any facts on which it based that estimate – to wit, the price at which any person or entity purchased *Avonex*® at any time.

<sup>2</sup> Further, with respect to the allegations regarding AWP, this Court has already ruled that to satisfy Rule 9(b) a plaintiff must allege “(1) the specific drug or drugs that were purchased from defendant; (2) the allegedly fraudulent AWP for each drug; and (3) the name of specific plaintiff(s) that purchased the drug.” In re Pharmaceutical Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172, 194 (D. Mass. 2003).

Simply listing a published AWP and then providing a conclusory “estimated true AWP” with no explanation at all of its source fails to satisfy Rule 9(b).

**B. Plaintiff Fails to Allege with Particularity that Biogen Failed to Provide the true AMP and BP for Avonex®.**

Suffolk County’s allegations regarding Biogen’s alleged failure to report the true AMP and BP for Avonex® are even more cursory. Suffolk County does not identify a single allegedly fraudulent reported AMP or BP for Avonex®, the name of the person who submitted such a false report, or the date of any such false report. Nor does Suffolk County explain why any reported AMP or BP for Avonex® was false. Rather, Suffolk County refers to various recent government investigations (*see id.* ¶¶ 92-93), *none of which involved Biogen or Avonex®*, and alleges that various discounts and rebates should have been factored in the calculation of AMP and BP (*id.* ¶ 84). However, Suffolk County does not identify with particularity any discount that Biogen gave to any purchaser, nor any “free goods” “education grants” “volume rebates” or “free samples” provided by Biogen at any time or to any entity. Suffolk County does not even allege with particularity that Biogen provides such inducements to market Avonex® generally.

**C. Plaintiff Fails to Allege With Particularity that Biogen “Markets the Spread” or Engages in Any Other Allegedly Fraudulent Conduct.**

The sole alleged motivation for the Medicaid fraud scheme described in the Complaint is that defendants “market the spread” and “motivate providers to distribute the drugs with the highest reimbursement rate.” (Suff. Cty. Compl. ¶ 10). Indeed, according to Suffolk County, in addition to the fraudulent reporting of AWP, BP and AMP, the fraud is effectuated by “marketing and promoting” drugs based on the ability to collect inflated “payments from the government.” (*Id.* ¶ 14.) However, Suffolk County *nowhere* alleges with particularity that Biogen “markets the spread” or otherwise promotes Avonex® based

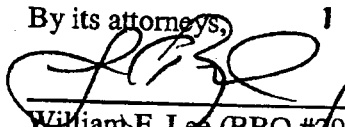
on the "spread." Nor does it describe any practices, meetings, memoranda or statements of Biogen to that effect. Moreover, in describing Biogen's alleged role in the RICO "Manufacturer-Publisher Enterprises" Suffolk County makes no specific allegation about Biogen, rather, it parrots the same allegations made against every other defendant which themselves simply recite the statutory requirements for a RICO enterprise. (Id. ¶ 341(i).) Suffolk County does not provide a single example of the alleged contractual relationship, financial ties or coordination between Biogen and any of the AWP publishers. (Id.)

### CONCLUSION

Suffolk County's failure to plead with particularity the who, what, where, when and how of Biogen's alleged fraudulent reporting of the AWP, AMP and BP for Avonex® dooms its fraud-based claims against Biogen. Suffolk County has not identified who made an allegedly fraudulent report, when such report was made, what the fraudulent report was or, most importantly, *why any reported AWP, AMP or BP was fraudulent*. Further, Suffolk County has failed to plead with particularity that Biogen "markets the spread" or has any relationship with the publishers of AWP. Barring such specificity, the fraud-based claims against Biogen do not satisfy Rule 9(b) and must be dismissed.

Respectfully submitted,  
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Dated: September 15, 2003

**#8**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

)  
)  
) MDL No. 1456

) Master File No. 01-CV-12257-PBS

THIS DOCUMENT RELATES TO:

) The Hon. Patti B. Saris

*County of Suffolk v. Abbott Laboratories, Inc.,*  
*et al.*, E.D.N.Y. Case No. 03-229-DRH

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**ELI LILLY AND COMPANY'S SEPARATE MEMORANDUM  
OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT**

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In addition to the reasons contained in the consolidated memorandum filed on behalf of all defendants, the Complaint should be dismissed as to Eli Lilly and Company ("Lilly") because, among other reasons, it fails completely to satisfy the requirements of Rule 9(b), Fed. R. Civ. P. In particular, the Complaint alleges that Lilly engaged in fraud and racketeering without specifying with particularity the circumstances constituting Lilly's alleged fraud and racketeering. Indeed, the allegations against Lilly -- that it overcharged and defrauded Suffolk County -- are completely false. For the purpose of this motion, this Court need not determine the truth or falsity of the allegations; rather, it may dismiss them because they are not plead with the required particularity.

"This Circuit takes very seriously the pleading requirements set forth in Rule 9(b) . . . ." *Lirette v. Shiva Corp.*, 27 F. Supp. 2d 268, 284 (D. Mass. 1998) (citation omitted). This Court previously dismissed claims by other plaintiffs in this multi-district action because they failed to meet the heightened pleading requirements of Rule 9(b). *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. May 13, 2003). The heightened pleading requirements apply not only to claims labeled "fraud," but also to all claims sounding in fraud. *See, e.g., Arruda v. Sears, Roebuck & Co.*, 310 F.3d 13, 18-19 (1<sup>st</sup> Cir. 2002) (Rule 9(b) applicable to claim under the Fair Debt Collection Practices Act); *McGinty v. Beranger Volkswagen, Inc.*, 633 F.2d 226, 228-29 (1<sup>st</sup> Cir. 1980) (Rule 9(b) applicable to claims under the Federal Odometer Act, the Massachusetts Odometer Act and the Massachusetts Consumer Protection Act).

In cases such as this involving multiple defendants, "each defendant's role must be particularized with respect to their alleged involvement in the fraud." *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp. 2d 70, 79 (D. Mass. 1998) (quotation omitted). "It is not

enough to salt the complaint with the words ‘falsely’ and ‘fraudulently.’” *Curtis v. Duffy*, 742 F. Supp. 34, 38 (D. Mass. 1990).

The Complaint should be dismissed because it relies exclusively upon general allegations levied against all defendants as a group, without specifying the particular wrongdoing allegedly committed by Lilly. The entire more than one-hundred-page Complaint contains no more than six paragraphs that refer specifically to Lilly. Complaint, ¶¶207-212. Of those six paragraphs, five contain nothing more than boilerplate and disfavored “information and belief” allegations. *Id.*, ¶¶207, 209-212.

The only paragraph in the entire Complaint that makes any attempt to particularize allegations against Lilly is paragraph 208. In that single paragraph, plaintiff alleges that Lilly’s “Reported Average Wholesale Price” for Prozac and Zyprexa exceeded “Suffolk’s Estimated True AWP.”

Yet, the allegations in paragraph 208 fall far short of the requirements of Rule 9(b). Most important, Suffolk does not explain how its “Estimated True AWP” numbers were derived, much less how or why Lilly’s reported prices supposedly were fraudulent. *See United States ex rel. Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347 (D. Mass. 1999) (dismissing Medicare fraud case under Rule 9(b) because plaintiff failed to allege why or how the defendant’s price representations were fraudulent). All of the key allegations in the Complaint against Lilly are conclusory and, therefore, inadequate. Simply restating an alleged AWP, and then baldly asserting that it is false and fraudulent, does not satisfy Rule 9(b). Suffolk is required to particularize how and why Lilly’s alleged prices are fraudulent, and it has failed to do so.

For all of these reasons, and for the reasons stated in defendants' consolidated memorandum, the Complaint should be dismissed as to Lilly.

Dated: September 15, 2003

Respectfully submitted,



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**#9**

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

**In Re Pharmaceutical Industry  
Average Wholesale Price Litigation**

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)  
) **MDL Docket No. 1456**

**THIS DOCUMENT RELATES TO:  
ALL ACTIONS**

) **Master File No. 01-CV-12257-PBS**

) **Judge Patti B. Saris**  
)

**MEMORANDUM IN SUPPORT OF MEDIMMUNE'S MOTION TO DISMISS<sup>1</sup>**

The amount Medicaid reimburses to a provider of a drug is a function of that drug's average wholesale price ("AWP"). If AWP increases, the spread between it and the actual cost of the drug to the provider also increases, yielding an increase in the amount reimbursed to the provider. Plaintiff alleges a scheme by drug companies to inflate AWP to create a larger spread for a given company's drug than a competitor can offer to potential purchaser/providers. Each company then allegedly "markets the spread" to their customers as enabling greater profit for the provider than any competing drug. *See e.g., Am. Comp. at ¶¶ 10, 13-17.*

But Synagis, the MedImmune, Inc. ("MI") drug at issue, stands alone in its field. It is the only drug that does what it does. It has no competitors. MedImmune therefore has no need to "beat" competitors or to market Synagis on any basis other than its unique effectiveness. Accordingly, plaintiff has not, and cannot, allege any facts to show that MI's conduct amounts to fraud or otherwise fits the basic paradigm of the Complaint's alleged AWP scheme – the

<sup>1</sup> Although MedImmune, Inc. is named as a defendant in only the Suffolk County case (and the Westchester replica of it not yet in this Court), MedImmune fully adopts all of the arguments advanced on behalf of all defendants in the Consolidated Motion to Dismiss and supporting Memorandum, as well as the arguments advanced in the joint and individual memoranda filed today by other "Suffolk-only" defendants like MedImmune, and by all other individual defendants.

paradigm which forms the basis for Counts I, IV, V, VII, VIII, and IX.<sup>2</sup> Indeed, in its Complaint, plaintiff allocates only two sentences to MedImmune and they utterly fail to supply the pleading particulars required by Rule 9(b).<sup>3</sup>

### ARGUMENT

#### **The "AWP Scheme" Allegations Against MI Do Not Meet the Particularity Requirements of Federal Rule of Civil Procedure 9(b).**

Plaintiff contends that the defendants developed the AWP scheme because they are motivated to exploit the desire of providers to use those drugs with the highest reimbursement rate. Am. Compl., at ¶ 10. But such a motivation cannot exist if there are no competing drugs that could yield equivalent or greater reimbursement. That there are no drugs at all competing with MI's Synagis is an unassailable fact. Synagis is the only drug that helps to prevent respiratory syncytial virus ("RSV") in premature infants.<sup>4</sup> Moreover, its predecessor drug, now completely supplanted in the marketplace by Synagis, was also manufactured by MI.

In naming MI as a defendant, plaintiff simply ignores this crucial fact that materially distinguishes MI from the other defendants in this action. Contrary to the particularity required by Federal Rule of Civil Procedure 9(b), plaintiff does little more than allege the scheme as if it were chargeable to every defendant. *See, e.g.*, Am. Compl., at ¶ 10. Since it paints with a broad non-particularized brush, plaintiff does not pause to set forth or consider the

<sup>2</sup> *See In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194, n.11 (D. Mass. 2003).

<sup>3</sup> Counts II, III, and VI of the Amended Complaint must also be dismissed because, although all defendants are abstractly charged with "failure to report best prices", Am. Compl., at ¶ 84, not a single particularized fact is alleged against MI on that subject. *See n. 6, infra*.

<sup>4</sup> Since only infants take Synagis, it can be a Medicaid drug, but Medicare law is irrelevant to it. Likewise off point is plaintiff's use of Medicare rhetoric as though it were applicable to all defendants. *See Joint Memorandum of "Suffolk-Only" defendants*.

special circumstances of MI or explain how MI – alone in its field – could ever have taken advantage of a scheme whose object is the creation of competitive advantage. Neither does plaintiff allege whether Synagis is deeply discounted from AWP. That is relevant to whether any impropriety exists at all because it will determine whether there is any significant profit a provider could expect, given the Medicaid formula which itself involves a discount from AWP. If the drug is not discounted to the provider by an amount greater than the amount produced by Medicaid's discount, there is no excess reimbursement to the provider at all. In that circumstance, an allegation of fraud would be preposterous. In addition, plaintiff also just ignores the statutory availability to the State of New York of all Medicaid pricing information, N.Y. Soc. Serv. Law § 367-a(7), and the black letter law that makes a claim of fraud based on misrepresentation untenable when there is such access to the relevant facts. *See Grumman Allied Indus. Inc. v. Rohr Indus. Inc.*, 748 F.2d, 737, n.13 (2d Cir. 1984).

Rule 9(b)'s heightened standards are strictly applied when fraud lies at the core of a claim, *New England Data Services, Inc. v. Becher*, 829 F.2d 286, 288 (1st Cir. 1987); *Ross v. Bolton*, 904 F.2d 819, 823 (2d Cir. 1990). To satisfy them, a plaintiff must allege "the circumstances constituting fraud . . . with particularity," Fed. R. Civ. P. 9(b), a standard plaintiff does virtually nothing to meet as to MI. Neither does plaintiff meet the pleading requirements imposed by the Court in this case. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003).

Perhaps most importantly, plaintiff does not even mention (or know?) that MI has no competitor that could generate the manipulative motivation other defendants are alleged to have shared. Instead, plaintiff supplies only conclusory and generalized allegations, applicable broadly across the board to all defendants, along with an alleged "estimated true AWP" of

unspecified and uncertain origin. See Am. Compl., at ¶ 258.<sup>5</sup> In fraud and related cases, the Federal Rules of Civil Procedure do not accept such pleading deficiencies and, accordingly, require the dismissal of Counts I, IV, V, VII, VIII, and IX against MI. It is firmly established that a complaint that fails to provide the who, what, when, where, and how of the alleged fraud must be dismissed under Rule 9(b). *Suna v. Bailey Corp.*, 107 F. 3d 64, 68 (1st Cir. 1997); *M & I Heat Transfer Products Ltd. v. Willke*, 131 F. Supp. 2d 256, 261 (D. Mass. 2001); *Van Schaick v. Church of Scientology of Cal. Inc.*, 535 F. Supp. 1125 (D. Mass. 1982).<sup>6</sup>

This Court spoke with unmistakable clarity about this point at the oral argument of January 13, 2003. "You've got to meet 9(b) requirements. You've got to particularize exactly what drugs, exactly what the fraud is, what plaintiffs paid for what drugs." Tr. of Jan. 13, 2003 Oral Arg., at 74 (emphasis supplied). An allegation that a price is fraudulent because it is not the same as an alleged, but unsupported, "true" price hypothesized by the pleader, does not come close to explaining "exactly what the fraud is." *Id.*

The specificity requirement is not a trivial technicality. It enables a defendant to know what to defend against. And perhaps as importantly, it ensures that potential defendants

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<sup>5</sup> Plaintiff alleges that in 2001, MI reported an AWP for Synagis of \$1,416.48, and asserts, without any particulars, that "based upon [plaintiff's] investigation," the 2001 "Estimated True AWP" for Synagis was \$932.96. Am. Compl., at ¶ 258. However, plaintiff fails to provide any detail as to how this "Estimated True AWP" was determined. An unsupported hypothesis does not satisfy the requirement to supply particulars. That need is especially pressing because there is AWP found in the law, and none pursuant to which plaintiff purports to calculate an "Estimated True AWP".

<sup>6</sup> As noted, *supra*, n.4, plaintiff does not identify a single allegedly fraudulently reported "best price" for Synagis, let alone particularize who submitted such a false report of the date of any such false report. Indeed the Amended Complaint is utterly devoid of any specific allegation that MI ever falsely reported Synagis' best prices or otherwise engaged in any fraud in its "best price" reporting. Accordingly, all counts against MI regarding "best price," -- Counts II, III, and VI, -- must be dismissed pursuant to Rules 9(b) and 12(b)(6).



will be spared the vexatious burdens of fraud litigation when there are insufficient facts, apparent at the pleading stage, to justify imposing such burdens.

In short, Rule 9(b) is about fairness which, in this instance, requires dismissal of MI from this case.

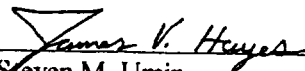
**CONCLUSION**

Because plaintiff does not plead with the particularity required by Rule 9(b) in a case such as this, its Amended Complaint, as against MedImmune, should be dismissed.

Respectfully submitted,

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Dated: September 15, 2003

Attorneys for Defendant MedImmune, Inc.

**#10**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE	)	MDL NO. 1456
WHOLESALE PRICE LITIGATION	)	C.A. No. 01-CV-12257 (PBS)
	)	
THIS DOCUMENT RELATES TO:	)	HON. PATTI B. SARIS
	)	
COUNTY OF SUFFOLK,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
ABBOTT LABORATORIES, INC., <i>et al.</i>	)	
	)	
Defendants.	)	
	)	

SEPARATE MEMORANDUM OF MERCK & CO., INC.  
IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT

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**SEPARATE MEMORANDUM OF MERCK & CO., INC.  
IN SUPPORT OF ITS MOTION TO DISMISS**

Defendant Merck & Co., Inc. ("Merck") submits this separate memorandum in support of its motion to dismiss the Amended Complaint (the "Complaint") for failure of the Complaint to state a claim against Merck. Merck also joins in the Consolidated Memorandum In Support Of Defendants' Motion To Dismiss (the "Consolidated Memorandum").

**I. SUFFOLK COUNTY HAS FAILED TO ALLEGE ANY FRAUDULENT CONDUCT BY MERCK**

Merck was dismissed from the Master Consolidated Complaint ("MCC") by this Court's Order of May 13, 2003 (the "May 13 Order"), and Merck was not named as a defendant in the plaintiffs' subsequent amended complaint. Citing no new factual allegations, and raising state-law issues that establish the absence of fraud, Suffolk County now seeks to bring Merck back into this litigation. Its attempt to do so fails entirely to satisfy the standard for pleading an AWP claim articulated in the May 13 Order, as well as the underlying standard of Fed. R. Civ. P. 9(b) and 12(b)(6).

Suffolk County's amended complaint relies on "examples" of allegedly improper conduct and on reports of investigations and judicial proceedings involving pharmaceutical pricing, but none of these involved any conduct of Merck's. (*E.g.*, Compl. ¶ 112.) Allegations of misconduct by one defendant, even when characterized as exemplary, are inadequate to satisfy even notice pleading requirements as to another defendant, much less the particularity of pleading required to support an allegation of fraud. As this Court made clear in its May 13 Order, litigation by association is not permitted. *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass 2003) (plaintiff must allege facts as to each defendant).

Suffolk County's so-called "investigation" (Compl. ¶ 259) has evidently failed to yield support for even one *allegation* of fraud or misconduct by Merck. This should not be

surprising. None of the investigations by “[t]he United States Department of Justice (“DOJ”), the United States General Accounting Office (“GAO”), the Office of the Inspector General at the United States Department of HHS (“OIG”), and certain Congressional subcommittees,” described in the Complaint (*id.* ¶ 108; *see also* ¶ 65), has produced a claim of wrongdoing by Merck. Nor has New York’s Attorney General, who has brought actions against other pharmaceutical companies relating to the same subject matter, *e.g.*, *People of the State of New York v. Aventis, Inc.*, D. Mass., 1:03-cv-11228 PBS, or the most recent Amended Master Consolidated Class Action Complaint, named Merck as a defendant.

The rules are clear. When it dismissed the MCC as against Merck and others, the Court cautioned that the plaintiffs must, in any amended complaint:

“clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug.” May 13 Order, 263 F. Supp. at 194.<sup>1</sup>

That ruling was foreshadowed during Oral Argument, when the Court said that Rule 9(b) requires a complaint to “particularize exactly what drugs, exactly what the fraud is, which plaintiffs paid for what drugs.” Tr. Oral Argument at 74 (Jan 13, 2003). Suffolk County has plainly failed to meet this standard as to Merck.

Although Suffolk County lists the published AWP for five Merck drugs, its attempt to characterize each AWP as “fraudulent” rests entirely on a figure of unexplained origin called “Suffolk’s Estimated True AWP.” This black box of a term is never defined and its use

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<sup>1</sup> The pleading requirements stated in the Court’s May 13 Order are essentially an application to the AWP Litigation of the well-known particularity-in-pleading requirement of Federal Rule 9(b). *E.g.*, *Hayduk v. Lanna*, 775 F.2d 441, 443-444 (1st Cir. 1985) (describing application of Rule 9(b) to state-law fraud claims).

cannot satisfy even the requirements of notice-pleading. An allegation that a price is fraudulent because it differs from the plaintiff's unsupported opinion of what the price ought to have been does not state a claim for fraud. *See* May 13 Order; Fed. R. Civ. P. 9(b). Moreover, the Complaint nowhere alleges any facts *as to Merck* that would describe "exactly what the fraud is." Instead, the Complaint sets forth a series of examples of alleged misconduct by other pharmaceutical manufacturers, followed by five paragraphs of boilerplate allegations about Merck that contain no description of any misconduct.<sup>2</sup> (Compl. ¶¶ 259-263.)

The same failure defeats Suffolk County's boilerplate allegations of fraud in connection with Merck's "Best Price" information. The Complaint states no facts that would support an inference that Merck violated the Best Price rules, or even that it engaged in conduct or activities similar to those alleged as to other manufacturers as regards Best Price. (Compl. ¶¶ 87, 89, 92-93.) The Complaint fails to identify any allegedly fraudulent Best Price submitted by Merck or the corresponding correct Best Price. Nor can Suffolk County claim (*id.* ¶ 262) that information about Best Prices is exclusively within Merck's control; as discussed in Section II, *infra*, all potentially relevant information was the State of New York's for the asking.

All of the Complaint's allegations as to Merck depend on the same we-know-but-won't-tell-you-why gimmick. The May 13 Order flatly prohibits such games. Merck has no place in this litigation, and the claims against it should be dismissed.

## II. THE COMPLAINT'S OWN ALLEGATIONS DEFEAT ANY CLAIM OF FRAUD

This Court dismissed Merck from the MCC because of the insufficiency of allegations related to AWP largely identical to those pleaded in this action. May 13 Order, 263

<sup>2</sup> The Complaint, for example, fails even to specify what Suffolk County paid for each Merck product or what rebates it received for each through the Medicaid rebate system.

F. Supp. 2d at 195. Suffolk County now alleges that “there is another aspect to the Medicaid Statutory Scheme implicated here,” and seeks to avoid the same fate on that basis. (Compl. ¶ 76.) However, it is precisely the other aspects of the Medicaid statutory scheme, detailed in the Complaint, that make Suffolk County’s allegations of fraud against Merck internally inconsistent and legally untenable, even if they had been pleaded with the required specificity.<sup>3</sup>

Suffolk County alleges that the defendants misrepresented AWP to be “an accurate reflection of average wholesale price paid for their drugs,” and to represent “[a]ctual transaction price data.” (Compl. ¶¶ 399(c), 67.) But other allegations of the Complaint make it clear that Suffolk County (or more properly New York State) could not reasonably have believed any such thing, and this precludes every one of the county’s fraud claims, *see, e.g., Brenner v. American Cyanamid Co.*, 732 N.Y.S.2d 799, 801 (App. Div. 2001) (fraud requires reliance), as well as its claims under New York’s Unfair Trade Practices law, *see S.Q.K.F.C., Inc. v. Bell Atl. Tricon Leasing Corp.*, 84 F.3d 629, 636 (2d Cir. 1996) (practice only misleading where a “reasonable consumer would have been misled by the defendant’s conduct”).

The Medicaid law requires New York to reimburse pharmacies for dispensing covered drugs at their “estimated acquisition cost.” (Compl. ¶¶ 71-73.) New York has concluded that this cost equals AWP “less a percentage discount,” which the legislature set at 10% (recently raised to 12%). (*Id.* ¶ 73 (citing N.Y. Soc. Serv. Law §367-a(9).) The legislative finding – in full accord with authorities cited in the Consolidated Memorandum and the Complaint itself – that AWP was substantially *in excess of* a drug’s estimated acquisition cost

<sup>3</sup> The Merck products identified in paragraph 259 of the Complaint are all single-source drugs purchased by Medicaid participants from pharmacies, and the arguments in this motion address only that aspect of the reimbursement scheme.

cannot be squared with Suffolk County's simultaneous claim that the defendants misrepresented AWP to be *equal to* actual market price. But the county's allegations of fraud depend on exactly this inconsistency.

The statutory power of the State of New York to demand drug pricing information from all manufacturers also makes Suffolk County's allegations of fraud untenable. N.Y. Soc. Serv. Law § 367-a(7) empowers the State to require "[e]very manufacturer or wholesaler of drugs . . . [to provide] upon request of the department . . . any information pertaining to wholesale prices charged to pharmacists for any drugs available" under the Medicaid program and to "make the requested information available to the department on a monthly basis." It is black letter law that a plaintiff's free access to relevant facts defeats a claim based on an alleged misrepresentation of those facts. *Grumman Allied Indus., Inc. v. Rohr Indus., Inc.*, 748 F.2d 729, 737 n.13 (2d Cir. 1984) (plaintiff must make use of "means available to him of knowing . . . the truth or the real quality of the subject of the representation" in order to claim misrepresentation (quoting *Danann Realty Corp. v. Harris*, 157 N.E.2d 597, 600 (N.Y. 1959))).

In the MCC, this Court determined that it would need to construe the federal statutory term "AWP."<sup>4</sup> Not so here, as that term is inapplicable to Medicaid. Rather, the plaintiff's claims here depend on an assertion that the defendants are liable for New York's independent decisions as to Medicaid drug reimbursement. New York's knowledge that AWPs are not market prices, and its ability to collect all Medicaid-related data from manufacturers, independently doom such a claim.

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<sup>4</sup> Indeed, the Court declined prudential abstention based on its need to construe an applicable federal statutory term. See May 13 Order, 263 F. Supp. at 180-81. Such is not the case here.



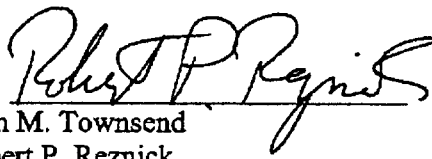
**CONCLUSION**

For the foregoing reasons, as well as those set forth in the Consolidated Memorandum, the Amended Complaint should be dismissed as to Merck & Co., Inc.

Dated: September 15, 2003.

Respectfully submitted,

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**#11**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESAL PRICE  
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257 PBS

THIS DOCUMENT RELATES TO:

Judge Patti B. Saris

*County of Suffolk v. Abbot Laboratories,  
Inc., et al.*

**MEMORANDUM OF LAW OF NOVARTIS PHARMACEUTICALS  
CORPORATION IN SUPPORT OF ITS MOTION TO DISMISS  
THE COUNTY OF SUFFOLK'S AMENDED COMPLAINT**

### INTRODUCTION

Novartis Pharmaceuticals Corporation ("NPC") is named with 36 other pharmaceutical companies and 100 "Does" in an Amended Complaint ("Complaint" or "Cplt.") brought by the County of Suffolk ("Suffolk"). Suffolk asserts nine causes of action against NPC and other defendants as part of its overall claim that "defendants have engaged in a systematic and pervasive fraudulent scheme with others in the pharmaceutical distribution chain . . . to collect inflated prescription drug payments from Suffolk." Cplt. ¶2. NPC joins in and incorporates by reference Defendants' Consolidated Motion and Memorandum of Law in Support of Their Motion to Dismiss the Complaint ("Def. Mem.") and the memoranda of individual defendants, which demonstrate that the Complaint must be dismissed in its entirety. NPC here demonstrates additional grounds for dismissal of NPC from Counts I-III, and V-VIII.

### ARGUMENT

#### **I. ALL FRAUD-BASED CLAIMS MUST BE DISMISSED UNDER FED. R. CIV. P. 9(b) AND 12(b)(6).**

The Complaint essentially relies on conclusory allegations that NPC fraudulently (1) failed to report "Best Price" to the federal Medicaid program and (2) reported false average wholesale prices ("AWPs") for certain drugs. Cplt. ¶2. Specifically, Count I asserts violations of the federal RICO statute (18 U.S.C. §1962[c]) in connection with individual "Manufacturer-Publisher Enterprises" allegedly conducted to disseminate pharmaceutical pricing information, including false and misleading AWP's. Cplt. ¶¶332-55. Counts II and III claim violations of federal and state law, respectively, for alleged failures to report Best Price. *Id.* ¶¶356-74. Count V asserts that defendants obtained public funds through false statements of drug prices in violation of New York Social Services Law. *Id.* ¶¶379-84. Count VII alleges unfair trade practices under N.Y. General Business Law §349 *et seq.* for fake or misleading reporting of AWP and Best Price. *Id.* ¶¶392-400. And Count VIII alleges that defendants intentionally committed fraud by reporting false AWP's. *Id.* ¶¶401-06. Each of these claims is fraud-based and, thus, subject to Fed. R. Civ. P. 9(b)'s requirement that a plaintiff must plead the elements of fraud with particularity. *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 (1st Cir. 1991) ("It is settled law in this circuit that Fed. R. Civ. P. 9[b] . . . extends to pleading predicate acts of mail and wire fraud under RICO."); *Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985) (Fed. R. Civ. P. 9[b] applies to state law fraud claims in federal court); *Varney v. R.J. Reynolds Tobacco Co.*, 118 F. Supp. 2d 63, 67 (D.

Mass. 2000) (citing *Hayduk, inter alia*) (“Even in cases removed from state court, the adequacy of pleadings is measured by the federal rules”).

Notably, the Complaint lacks any specific allegations of wrongdoing by NPC, which is named in six of the 419 paragraphs of the Complaint (*i.e.*, ¶¶44, 264-67, 341[u]). The *sole* NPC drug identified in the Complaint is Clozaril, as to which Suffolk merely alleges that 1.4% of its “Medicaid Pharmacy Costs” are attributed to Clozaril. *Id.* ¶¶44, 264; Ex. B. As Clozaril is a multiple source drug, all claims relating to this drug should be dismissed for the reasons set forth in Def. Mem., Point I.D. Further, Suffolk nowhere pleads the price reported by NPC as the Best Price for Clozaril. Nor does Suffolk plead the AWP published for Clozaril. *Moreover, Suffolk has not included Clozaril in its Exhibit A schedule of “Suffolk Medicaid Overcharges Drug by Drug” or otherwise identified “Suffolk’s estimated true AWP” for Clozaril. Significantly, Suffolk nowhere alleges a fraudulent Best Price or AWP for Clozaril, much less pleads how such Best Price or AWP is fraudulent.* Nor are there any such allegations for any other NPC drug, since Clozaril is the only NPC drug identified in the Complaint. As this Court has held, fraud claims based on named drugs without a specified fraudulent AWP and on unnamed drugs must be dismissed. *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) (Saris, J.).

It is equally “well settled” in this Circuit that Rule 9(b) requires that the “time, place, and content of an alleged false representation” be pled with specificity. *Wayne Inv., Inc. v. Gulf Oil Corp.*, 739 F.2d 11, 13 (1st Cir. 1984) (citation omitted); *accord Suna v. Bailey Corp.*, 107 F.3d 64, 68, 73 (1st Cir. 1997); *see also Vicom, Inc. v. Harbridge Merchant Servs., Inc.*, 20 F.3d 771, 778 (7th Cir. 1994) (in a case involving multiple defendants, the complaint must inform each defendant of the specific alleged fraud by that particular defendant). Moreover, where allegations of fraud are based merely on “information and belief” (Cplt. at introductory paragraph, ¶264), the complaint also must “set forth a factual basis for such belief.” *U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (Saris, J.) (citation omitted) (dismissing *qui tam* complaint alleging that vendors submitted invoices to hospitals that did not reflect discounts and credits – causing the hospitals to submit false claims for Medicare reimbursement – where relator did not identify specific sales or

claims for payment that were allegedly fraudulent and did not plead the source of his information or the reasons for his beliefs); *see also Wayne Investment, Inc.*, 739 F.2d at 13-14.

Suffolk has failed to particularize its claims that NPC fraudulently reported Best Prices; it has not identified (i) specific reports by which NPC allegedly failed to provide accurate Best Prices, (ii) any allegedly fraudulent statements, or (iii) why they were fraudulent. Because the Complaint does not identify a single incident of a false Best Price reported by NPC, Suffolk "has not met even a bare-bones Rule 9(b) test." *Walsh*, 98 F. Supp. 2d at 147 (citation omitted). Suffolk likewise has not met the Rule 9(b) test with regard to its AWP-based fraud allegations; it does not identify (i) the NPC drugs on which it bases its claims, (ii) the allegedly fraudulent AWP for each such drug, or (iii) how such AWP allegedly is fraudulent. As this Court stated to plaintiffs during the January 13, 2003 oral argument in connection with defendants' motion to dismiss the AWP multi-district class action litigation: "You've got to meet 9(b) requirements. You've got to particularize exactly what drugs, exactly what the fraud is . . . ." *In re Average Wholesale Price Pharm. Litig.*, Tr. of Hearing on Motions at 74 (Jan. 13, 2003); *see also In re Pham. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d at 194. Suffolk completely fails to meet this test.

The Complaint's repeated allegation that all defendants collectively engaged in an "AWP pricing scheme" does not and cannot satisfy Rule 9(b) with respect to NPC. As the *Hayduk* court held, "mere allegations of fraud, corruption or conspiracy, averments to conditions of mind, or referrals to plans and schemes are too conclusional to satisfy the particularity requirement, no matter how many times such accusations are repeated." 775 F.2d at 444 (citations omitted); *see also Varney*, 118 F. Supp. 2d at 68 (citing *Hayduk* and Rule 9[b]) ("Pleadings which portray a conspiracy to defraud or conceal may not be painted in broad strokes; they must state the factual foundations of that claim with particularity.").

Suffolk also fails to satisfy Rule 9(b) pleading requirements as to its RICO claim. As the *Feinstein* court held: "As in any other fraud case, the [RICO] pleader is required to 'go beyond a showing of fraud and state the time, place and content of the alleged mail and wire communications perpetrating that fraud.'" 942 F.2d at 42 (citation omitted). At a minimum, the pleader must provide "additional detail as to when the communications occurred, where they took place, or what they contained." *Id.* Here, any such "rudimentary information" (*id.*)